NO SUMMONS ISSUED

UNITED STATES DISTRICT COURT

EASTERN DISTRICT OF NEW YORK

UNITED STATES OF AMERICA,

Plaintiff,

v.

VENUS PHARMACEUTICALS INTERNATIONAL, INC., a corporation, and BHARAT KAKUMANU, an individual,

Defendants.

COMPLAINT FOR PERMANENT INJUNCTION

SPATT, J.

CIVIL ACTION NO. WALL, M.J.

Plaintiff, the United States of America, by Loretta E. Lynch, United States Attorney for the Eastern District of New York, respectfully represents to this Honorable Court as follows:

INTRODUCTION

1. This action is brought by the United States of America pursuant to the Federal Food, Drug, and Cosmetic Act (the "Act"), 21 U.S.C. § 332(a), and the equitable authority of this Court, to enjoin and restrain Venus Pharmaceuticals International, Inc., a corporation ("Venus"), and Bharat Kakumanu, an individual (collectively, "Defendants"), from violating:

a. 21 U.S.C. § 331(a), by introducing or delivering for introduction into interstate commerce, and causing the introduction or delivery for introduction into interstate commerce, articles of food (dietary supplements, as defined at 21 U.S.C. § 321(ff)) that are adulterated within the meaning of 21 U.S.C. § 342(g)(1); and

b. 21 U.S.C. § 331(k), by causing articles of food (dietary supplements, as defined at 21 U.S.C. § 321(ff)) to become adulterated within the meaning of 21 U.S.C. § 342(g)(1), while such articles are held for sale after shipment of one or more of their components in interstate commerce.

JURISDICTION AND VENUE

2. This Court has jurisdiction pursuant to 21 U.S.C. § 332(a) and 28 U.S.C. §§ 1331, 1337, and 1345, and personal jurisdiction over all parties.

3. Venue in this District is proper pursuant to 28 U.S.C. §§ 1391(b) and (c).

DEFENDANTS

4. Defendant Venus is a New York corporation with its principal place of business at 55-A Kennedy Drive, Hauppauge, NY 11788 (the "Facility"), within the jurisdiction of this Court.

5. Individual Defendant Bharat Kakumanu is Venus's Chief Executive Officer.

6. Defendant Kakumanu is responsible for Venus's business operations, including employee training, regulatory affairs, formulations, and manufacturing operations. Defendant Kakumanu has the duty to prevent, detect, and correct violations of the Act and the authority to hire and fire employees. Defendant Kakumanu performs his duties at the Facility, within the jurisdiction of this Court.

7. Defendants have been, and are now engaged in, manufacturing, preparing, labeling, packing, holding, and distributing "dietary supplements" within the meaning of 21 U.S.C. § 321(ff). Such products include, but are not limited to, Rockin' Wellness Whey Protein Powder, Tonic Alchemy Blend, Whey Protein Chocolate Powder, and GI Complete.

8. Defendants regularly manufacture dietary supplements using components, such as L. Glutamine powder, that they receive from outside New York. Defendants also introduce or deliver for introduction into interstate commerce finished dietary supplements.

DEFENDANTS ADULTERATE THEIR DIETARY SUPPLEMENTS

9. The United States Food and Drug Administration ("FDA") inspected Defendants' facility from January 13 through 20, 2012. This inspection established that the dietary supplements that Defendants manufacture, prepare, pack, label, hold, and distribute are adulterated within the meaning of 21 U.S.C. § 342(g)(1), in that they have been prepared, packed, and held under conditions that do not comply with the current good manufacturing practice ("cGMP") regulations for dietary supplements set forth at 21 C.F.R. Part 111.

10. Manufacturing in compliance with cGMP means that the manufacturer incorporates a set of controls in the design and production processes to ensure a consistent quality, finished product. Dietary supplements not prepared, packed, or held in conformance with cGMP are deemed adulterated. 21 U.S.C. § 342(g)(1).

11. During the January 2012 inspection, FDA investigators documented numerous deviations from cGMP. These deviations include, but are not limited to, the following:

a. Defendants failed to establish identity specifications for each dietary supplement component, in violation of 21 U.S.C. § 111.70(b);

b. Defendants failed to conduct at least one appropriate test or examination to verify the identity of any component that is a dietary ingredient, in violation of 21 U.S.C. § 111.75(a)(1)(i);

c. Defendants failed to first qualify the component supplier by establishing the reliability of the supplier's certificate of analysis through confirmation of the results of the supplier's tests or examinations, in violation of 21 U.S.C. § 111.75(a)(2)(ii)(A);

d. Defendants failed to establish in-process specifications for any point, step, or stage in the master manufacturing record where control is necessary to help ensure that

specifications are met for the identity, purity, strength, and composition of the dietary supplements and for limits on those types of contamination that may adulterate or may lead to adulteration of the finished batch of the dietary supplement, in violation of 21 U.S.C. § 111.70(c)(1);

e. Defendants failed to determine whether in-process specifications are met, in violation of 21 U.S.C. § 111.75(b)(1);

f. Defendants failed to establish product specifications for the identity, purity, strength, and composition of the finished batch of the dietary supplement, and for limits on those types of contamination that may adulterate or lead to the adulteration of the finished batch of the dietary supplement, to ensure quality of the dietary supplement, in violation of 21 U.S.C. § 111.70(e);

g. Defendants failed to select one or more established specifications, as required by 21 C.F.R. § 111.70(e), that, if tested or examined on the finished batches of the dietary supplement, would verify that the product and process control system is producing a dietary supplement that meets all product specifications, in violation of 21 C.F.R. § 111.75(c);

h. Defendants failed to establish written procedures for laboratory operations, including written procedures for tests and examinations to determine whether specifications are met, in violation of 21 U.S.C. § 111.303; and

i. Defendants' quality control personnel approved and released for distribution batches of dietary supplements that did not meet established product specifications, in violation 21 U.S.C. § 111.123(b)(2).

12. At the conclusion of the January 2012 inspection, the FDA investigators issued to Defendant Kakumanu a List of Inspectional Observations ("Form FDA 483"), detailing

Defendants' numerous violations of the Act and cGMP requirements, and discussed the documented observations with him.

13. The cGMP deviations documented during FDA's January 2012 inspection establish that Defendants' dietary supplements are adulterated within the meaning of 21 U.S.C. § 342(g)(1).

14. Defendants violate 21 U.S.C. § 331(a) by introducing or delivering for introduction into interstate commerce, and causing the introduction or delivery for introduction into interstate commerce, articles of food (dietary supplements) that are adulterated within the meaning of 21 U.S.C. § 342(g)(1).

15. Defendants violate 21 U.S.C. § 331(k) by causing articles of food (dietary supplements) to become adulterated within the meaning of 21 U.S.C. § 342(g)(1), while such articles are held for sale after shipment of one or more of their components in interstate commerce.

DEFENDANTS' HISTORY OF VIOLATIONS

16. Defendants are well aware, and have acknowledged, that their operations deviate from the cGMP regulations and that their failure to cease their violative conduct and implement corrections could lead to regulatory action.

17. FDA previously inspected Defendants' facility between July 6 and 12, 2011, and between August 16 and 19, 2010. During both inspections, FDA observed significant violations of the Act and cGMP regulations. During these inspections, the FDA investigators found some of the same and similar violations as those observed during the January 2012 inspection of the Facility, including, but not limited to, violations involving: failure to conduct identity testing for dietary supplement components, 21 C.F.R. § 111.75(a)(1)(i); failure to test finished product to

confirm established specifications are being met, 21 C.F.R. § 111.75(c); and failure of quality control personnel to withhold approval and release for distribution batches of dietary supplements that did not meet established product specifications, 21 C.F.R. § 111.123(b)(2).

18. At the conclusion of the August 2010, July 2011, and January 2012 inspections, the FDA investigators issued to Defendant Kakumanu a List of Inspectional Observations ("Form FDA 483"), detailing Defendants' numerous violations of the Act and cGMP requirements, and discussed the documented observations with him.

19. Defendants submitted written responses dated February 6, 2012, July 28, 2011, and September 7, 2010, to the Forms FDA-483 issued following the January 2012, July 2011, and August 2010 FDA inspections, respectively. In the written responses, Defendants acknowledged their violative conduct and promised to implement immediate corrections.

20. On May 4, 2011, FDA issued a Warning Letter to Defendant Kakumanu, informing him that the significant cGMP violations that FDA documented during the August 2010 inspection rendered Defendants' dietary supplements adulterated under the Act. The Warning Letter further cautioned Defendants that their failure to correct the violations promptly, and prevent future violations, could lead to additional regulatory action, including an injunction of their operations.

21. Defendants responded to the Warning Letter by letter dated May 23, 2011. Defendants acknowledged the firm's violations and promised that Defendants would achieve full cGMP compliance. As discussed above, FDA has since conducted two inspections in July 2011 and January 2012, and both revealed new and recurrent violations of the Act and cGMP regulations that were detailed in the May 2011 Warning Letter.

22. Based on their repeated course of conduct, Defendants, unless restrained by order of this Court, will continue to violate 21 U.S.C. §§ 331(a) and (k).

WHEREFORE, Plaintiff respectfully requests that the Court:

I. Order that Defendants, and each and all of their directors, officers, agents, representatives, employees, attorneys, successors, assigns, and any and all persons or entities in active concert or participation with any of them, cease manufacturing, preparing, processing, packing, labeling, holding, and/or distributing dietary supplements at or from their Facility or at or from any other location(s) at which Defendants manufacture, prepare, process, pack, label, hold, and/or distribute dietary supplements, now or in the future, unless and until Defendants bring their manufacturing, preparing, processing, packing, labeling, holding, and/or distributing operations into compliance with the Act and cGMP;

II. Order that Defendants, and each and all of their directors, officers, agents, representatives, employees, attorneys, successors, assigns, and any and all persons or entities in active concert or participation with any of them, be permanently restrained and enjoined under 21 U.S.C. § 332(a), from directly or indirectly doing or causing to be done any of the following acts:

A. Violating 21 U.S.C. § 331(a), by introducing or delivering for introduction into interstate commerce, and causing the introduction or delivery for introduction into interstate commerce, dietary supplements that are adulterated within the meaning of 21 U.S.C. § 342(g)(1); and

B. Violating 21 U.S.C. § 331(k), by causing dietary supplements to become adulterated within the meaning of 21 U.S.C. § 342(g)(1), while such articles are held for sale after shipment of one or more of their components in interstate commerce;

III. Order that FDA be authorized pursuant to this injunction to inspect Defendants' places of business and all records relating to the manufacturing, preparing, processing, packing, labeling, holding, and distribution of all of Defendants' dietary supplements to ensure continuing compliance with the terms of the injunction, with the costs of such inspections to be borne by Defendants at the rates prevailing at the time the inspections are accomplished; and

IV. Order that Plaintiff be awarded costs incurred in pursuing this action, including the costs of investigation to date, and such other equitable relief as the Court deems just and proper.

Dated this 9th day of October, 2012.

Respectfully submitted,

STUART F. DELERY
Acting Assistant Attorney General

LORETTA E. LYNCH
United States Attorney

By: Thomas D. McFarland

THOMAS MCFARLAND
Assistant U.S. Attorney
U.S. Attorney's Office
610 Federal Plaza
Central Islip, NY 11722

MAAME EWUSI-MENSAH FRIMPONG
Deputy Assistant Attorney General

MICHAEL S. BLUME
Director

JILL P. FURMAN
Deputy Director

By: _____
KATHRYN M. DRENNING
Trial Attorney
Consumer Protection Branch
Department of Justice, Civil Division
P.O. Box 386
Washington, D.C. 20044
Tel. (202) 353-2809
Fax (202) 514-8742
kathryn.m.drenning@usdoj.gov

Of Counsel:

WILLIAM B. SCHULTZ
Acting General Counsel

ELIZABETH H. DICKINSON
Associate General Counsel
Food and Drug Division

ERIC M. BLUMBERG
Deputy Chief Counsel for Litigation

JILLIAN WEIN RILEY
Assistant Chief Counsel for Enforcement
United States Department of Health and
Human Services